§ 101.108

- (2) The product shall be labeled on the outside of its shipping container with the statement(s):
- (i) When the variation concerns net weight and/or drained weight or volume, "Product Mislabeled. Actual net weight (drained weight or volume where appropriate) may be as low as __% below labeled quantity. This Product Not for Retail Distribution", the blank to be filled in with the maximum percentage variance between the labeled and actual weight or volume of contents of the individual packages in the shipping container, and
- (ii) When the variation is in regard to a fill of container standard, "Product Mislabeled. Actual fill may be as low as —% below standard of fill. This Product Not for Retail Distribution".
- (3) The statements required by paragraphs (t)(2) (i) and (ii) of this section, which may be consolidated where appropriate, shall appear prominently and conspicuously as compared to other printed matter on the shipping container and in boldface print or type on a clear, contrasting background in order to render them likely to be read and understood by the purchaser under ordinary conditions of purchase.

 $[42\ {\rm FR}\ 14308,\ {\rm Mar.}\ 15,\ 1977,\ {\rm as\ amended}\ {\rm at}\ 42\ {\rm FR}\ 15673,\ {\rm Mar.}\ 22,\ 1977]$

§ 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

- (a) The food industry is encouraged to experiment voluntarily, under controlled conditions and in collaboration with the Food and Drug Administration, with and other formats for presenting nutrition and other related food labeling information that is consistent with the current quantitative system in §§101.9 and 105.66 of this chapter.
- (b) Any firm that intends to undertake a labeling experiment that requires exemptions from certain requirements of §§101.9 and 105.66 of this chapter should submit a written proposal containing a thorough discussion of each of the following information items that apply to the particular experiment:
- (1) A description of the labeling format to be tested:

- (2) A statement of the criteria to be used in the experiment for assigning foods to categories, e.g., nutrient or other values defining "low" and "reduced":
- (3) A draft of the material to be used in the store, e.g., shelf tags, booklets, posters, etc.;
- (4) The dates on which the experiment will begin and end and on which a written report of analysis of the experimental data will be submitted to FDA, together with a commitment not continue the experiment beyond the proposed ending date without FDA approval;
- (5) The geographic area or areas in which the experiment is to be conducted:
- (6) The mechanism to measure the effectiveness of the experiment;
- (7) The method for conveying to consumers the required nutrition and other labeling information that is exempted from the label during the experiment;
- (8) The method that will be or has been used to determine the actual nutritional characteristics of foods for which a claim is made; and
- (9) A statement of the sections of the regulations for which an exemption is sought.
- (c) The written proposal should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The proposal should be clearly identified as a request for a temporary exemption for purposes of conducting authorized food labeling experiments and submitted as a citizen petition under §10.30 of this chapter.
- (d) Approval for food labeling experiments will be given by FDA in writing. Foods labeled in violation of existing regulations will be subject to regulatory action unless an FDA-approved exemption to the specific regulation has been granted for that specific product.
- (e) Reporting requirements contained in §101.108(b) have been approved by this Office of Management and Budget and assigned number 0910-0151.
- [48 FR 15240, Apr. 8, 1983, as amended at 59 FR 14364, Mar. 28, 1994; 62 FR 15343, Mar. 31,

Food and Drug Administration, HHS

APPENDIX A TO PART 101—MONIER-WILLIAMS PROCEDURE (WITH MODIFICATIONS) FOR SULFITES IN FOOD, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION (NOVEMBER 1985)

The AOAC official method for sulfites (Official Methods of Analysis, 14th Edition, 20.123–20.125, Association of Official Analytical Chemists) has been modified, in FDA laboratories, to facilitate the determination of sulfites at or near 10 ppm in food. Method instructions, including modifications, are described below.

Apparatus—The apparatus shown diagrammatically (Figure 1) is designed to accomplish the selective transfer of sulfur dioxide from the sample in boiling aqueous hydrochloric acid to a solution of 3% hydrogen peroxide. This apparatus is easier to assemble than the official apparatus and the back pressure inside the apparatus is limited to the unavoidable pressure due to the height of the 3% $\rm H_2O_2$ solution above the tip of the bubbler (F). Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks.

The apparatus should be assembled as shown in Fig. 1 with a thin film of stopcock grease on the sealing surfaces of all the joints except the joint between the separatory funnel and the flask. Each joint should be clamped together to ensure a complete seal throughout the analysis. The separatory funnel, B, should have a capacity of 100 ml or greater. An inlet adapter, A, with a hose connector (Kontes K-183000 or equivalent) is required to provide a means of applying a head of pressure above the solution. (A pressure equalizing dropping funnel is not recommended because condensate, perhaps with sulfur dioxide, is deposited in the funnel and the side arm.) The round bottom flask, C, is a 1000 ml flask with three 24/40 tapered joints. The gas inlet tube, D, (Kontes K-179000 or equivalent) should be of sufficient length to permit introduction of the nitrogen within 2.5 cm of the bottom of the flask. The Allihn condenser, E, (Kontes K-431000-2430 or equivalent) has a jacket length of 300 mm. The bubbler, F, was fabricated from glass according to the dimensions given in Fig. 2. The 3% hydrogen peroxide solution can be contained in a vessel, G, with an i.d. of ca. 2.5 cm and a depth of 18 cm.

Buret—A 10 ml buret (Fisher Cat. No. 03–848–2A or equivalent) with overflow tube and hose connections for an Ascarite tube or equivalent air scrubbing apparatus. This will permit the maintenance of a carbon dioxide-free atmosphere over the standardized 0.01N sodium hydroxide.

Chilled Water Circulator—The condensor must be chilled with a coolant, such as 20% methanol-water, maintained at 5 °C. A circu-

lating pump equivalent to the Neslab Coolflow 33 is suitable.

Reagents

- (a) Aqueous hydrochloric acid, 4N.—For each analysis prepare 90 ml of hydrochloric acid by adding 30 ml of concentrated hydrochloric acid (12N) to 60 ml of distilled water.
- (b) Methyl red indicator—Dissolve 250 mg of methyl red in 100 ml ethanol.
- (c) Hydrogen peroxide solution, 3%—Dilute ACS reagent grade 30% hydrogen peroxide to 3% with distilled water. Just prior to use, add three drops of methyl red indicator and titrate to a yellow end-point using 0.01N sodium hydroxide. If the end-point is exceeded discard the solution and prepare another 3% $\rm H_2O_2$ solution.
- (d) Standardized titrant, 0.01N NaOH—Certified reagent may be used (Fisher SO-5-284). It should be standardized with reference standard potassium hydrogen phthalate.
- (e) Nitrogen—A source of high purity nitrogen is required with a flow regulator that will maintain a flow of 200 cc per minute. To guard against the presence of oxygen in the nitrogen, an oxygen scrubbing solution such as an alkaline pyrogallol trap may be used. Prepare pyrogallol trap as follows:
 - 1. Add 4.5 g pyrogallol to the trap.
- 2. Purge trap with nitrogen for 2 to 3 min-
- 3. Prepare a KOH solution prepared by adding 65g KOH to 85 ml distilled water (caution: heat).
- 4. Add the KOH solution to the trap while maintaining an atmosphere of nitrogen in the trap.

Determination

Assemble the apparatus as shown in Fig. 1. The flask C must be positioned in a heating mantle that is controlled by a power regulating device such as Variac or equivalent. Add 400 ml of distilled water to flask C. Close the stopcock of separatory funnel, B, and add 90 ml of 4N hydrochloric acid to the separatory funnel. Begin the flow of nitrogen at a rate of 200±10 cc/min. The condenser coolant flow must be initiated at this time. Add 30 ml of 3% hydrogen peroxide, which has been titrated to a yellow end-point with 0.01N NaOH, to container G. After fifteen minutes the apparatus and the distilled water will be thoroughly de-oxygenated and the apparatus is ready for sample introduction.

Sample preparation (solids)—Transfer 50 g of food, or a quantity of food with a convenient quantity of SO_2 (500 to 1500 meg SO_2), to a food processor or blender. Add 100 ml of 5% ethanol in water and briefly grind the mixture. Grinding or blending should be continued only until the food is chopped into pieces small enough to pass through the 24/40 point of flask C.

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Pt. 101, App. A

Sample preparation (liquids)—Mix 50 g of the sample, or a quantity with a convenient quantity of SO_2 (500 to 1500 mcg SO_2), with 100 ml of 5% ethanol in water.

Sample introduction and distillation—Remove the separatory funnel B, and quantitatively transfer the food sample in aqueous ethanol to flask C. Wipe the tapered joint clean with a laboratory tissue, apply stopcock grease to the outer joint of the separatory funnel, and return the separatory funnel, B, to tapered joint flask C. The nitrogen flow through the 3% hydrogen peroxide solution should resume as soon as the funnel, B, is re-inserted into the appropriate joint in flask C. Examine each joint to ensure that it is sealed.

Apply a head pressure above the hydrochloric acid solution in B with a rubber bulb equipped with a valve. Open the stopcock in B and permit the hydrochloric acid solution to flow into flask C. Continue to maintain sufficient pressure above the acid solution to force the solution into the flask C. The stopcock may be closed, if necessary, to pump up the pressure above the acid and then opened

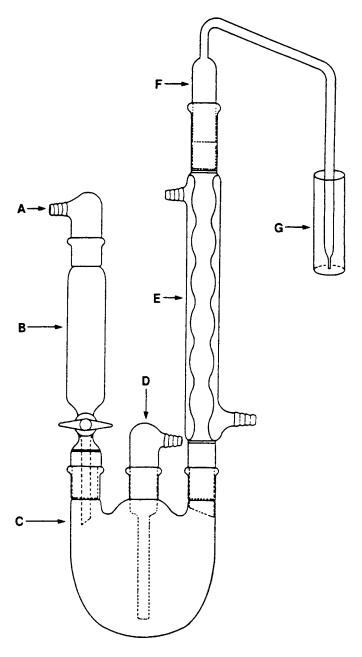
again. Close the stopcock before the last few milliliters drain out of the separatory funnel, B, to guard against the escape of sulfur dioxide into the separatory funnel.

Apply the power to the heating mantle. Use a power setting which will cause 80 to 90 drops per minute of condensate to return to the flask from condenser, E. After 1.75 hours of boiling the contents of the 1000 ml flask and remove trap G.

Titration.—Titrate the contents with 0.01N sodium hydroxide. Titrate with 0.01N NaOH to a yellow end-point that persists for at least twenty seconds. Compute the sulfite content, expressed as micrograms sulfur dioxide per gram of food (ppm) as follows:

 $ppm = (32.03xV_B xNx1000) \div Wt$

where 32.03=milliequivalent weight of sulfur dioxide; V_B =volume of sodium hydroxide titrant of normality, N, required to reach endpoint; the factor, 1000, converts milliequivalents to microequivalents and Wt=weight (g) of food sample introduced into the 1000 ml flask.



 $\label{prop:continuous} \mbox{Figure 1. The optimized Monier-Williams apparatus. Component identification is given in text. }$



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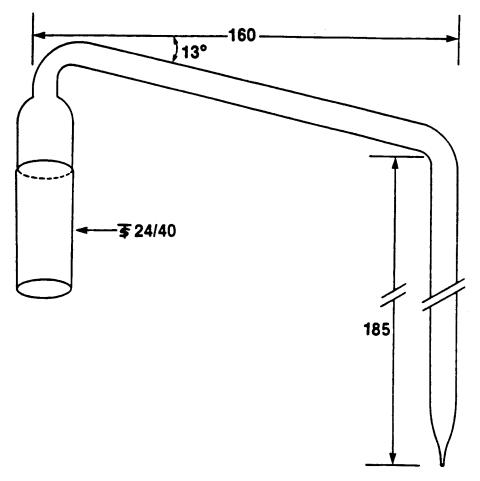


Figure 2. Diagram of bubbler (F in Figure 1). Lengths are given in mm. [42 FR 14308, Mar. 15, 1977, as amended at 51 FR 25017, July 9, 1986]

APPENDIX B TO PART 101—GRAPHIC ENHANCEMENTS USED BY THE FDA

Examples of Graphic Enhancements used by the FDA

A.Overall

 Nutrition Facts Label is boxed with all black or one color type printed on a white or neutral ground.

B. Typeface and size

- 1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats the typography may be kerned as much as -4, (tighter kerning reduces legibility).
- 2. Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but "%" is set in Helvetica Regular).
- 3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.
- "Serving Size" and "Servings per container" are set in 8 point Helvetica Regular with 1 point of leading.
- 5. The table labels (for example; "Amount per Serving") are set 6 point Helvetica Black.
- Absolute measures of nutrient content (for example; "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.
- 7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets.
- 8. All type that appears under vitamins and minerals is set in 6 point Helvetica regular with 1 point of leading.

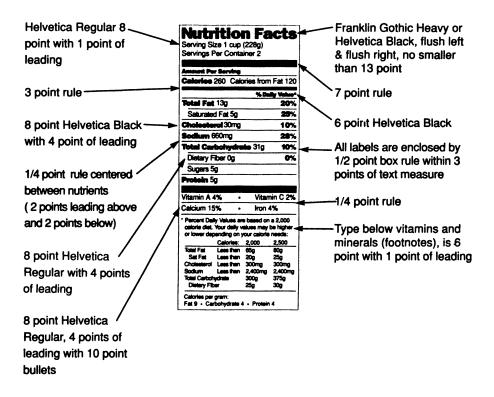
C. Rules

- A 7 point rule separates large groupings as shown in example. A 3 point rule separates calorie information from the nutrient information.
- 2. A hairline rule or 1/4 point rule separates individual nutrients, as shown in the example. Descenders do not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules.

D. Box

1. All labels are enclosed by 1/2 point box rule within 3 points of text measure.

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[58 FR 17332, Apr. 2, 1993]

		To		Total fat		Saturated		Cholesterol		lium	Potassium		Total Car-		Dietary		Sug-	Pro-	Vita-	Vita-	Cal-	Iron
Nutrition facts 1 for raw fruits and vege-	Cal-	Cal- ories from fat	TOLA	i iai		at	Onoic	310101	000	lium	1 Otas	SSIUIII		drate	Fit		ars	tein	min	min	cium	
tables edible portion	ories		(g)	(%)	(g)	(%)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)	(g)	(g)	(%)	(%)	(%)	(%)
Banana, 1 medium (126 g/4.5 oz) Apple, 1 medium (154 g/5.5 oz) Watermelon, ½18 medium melon; 2	110 80	0	0 0	0	0	0	0	0	0	0 0	400 170	11 5	29 22	10 7	4 5	16 20	21 16	1 0	0 2	15 8	0	2 2
cups diced pieces (280 g/10.0 oz) Orange, 1 medium (154 g/5.5 oz) Cantaloupe, ½ medium (134 g/4.8 oz) Grapes, 1½ cups (138 g/4.9 oz) Grapefruit, ½ medium (154 g/5.3 oz) Strawberries, 8 medium (147 g/5.3 oz) Peach, 1 medium (98 g/3.5 oz) Pear, 1 medium (166 g/5.9 oz)	80 70 50 90 60 45 40 100	0 0 0 10 0 0	0 0 0 1 0 0	0 0 0 2 0 0 0	0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0	10 0 25 0 0 0	0 0 1 0 0 0	230 260 280 270 230 270 190 210	7 7 8 8 7 8 5 6	27 21 12 24 16 12 10 25	9 7 4 8 5 4 3 8	2 7 1 6 4 2 4	8 28 4 4 24 16 8	25 14 11 23 10 8 9	1 1 1 1 1 1 1	20 2 100 2 15 0 2	25 130 80 25 110 160 10	2 6 2 2 2 2 0 2	4 2 2 2 0 4 0 0
Nectarine, 1 medium (140 g/5.0 oz) Honeydew Melon, ½10 medium melon (134 g/4.8 oz)	70 50	0	0.5 0	0	0	0	0	0	35	0	300 310	9	16 13	5 4	2 1	8	12 12	1	4	15 45	0	2
Plums, 2 medium (132 g/4.7 oz) Avocado, California, ½ medium (30 g/ 1.1 oz) Lemon, 1 medium (58 g/2.1 oz)	55 15	10 45 0	1 5 0	8 0	0 1 0	5 0	0 0	0 0	0 0 5	0 0	170 90	5 3	19 3 5	6 1 2	2 3 1	12 4	10 0 1	1 1 0	6 0 0	20 4 40	0 0 2	0 0
Pineapple, 2 slices, 3" diameter, 3/4" thick (112 g/4 oz)	60 50	0	0 0.5	0	0	0	0	0	10 0	0	115 180	3 5	16 15	5 5	1 3	4 12	13 12	1 1	0	25 50	2 4	2
(140 g/5.0 oz)	90 100 20 100	0 10 0 0	0.5 1 0 0	1 2 0 0	0 0 0	0 0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	300 480 75 720	9 14 2 21	22 24 7 26	7 8 2 9	3 4 2 3	12 16 8 12	19 16 0 3	2 2 0 4	2 2 0 0	15 240 35 45	2 6 0 2	2 4 0 6
3.2 oz)	15 35 60	0 0 0	0 0.5 0	0 1 0	0 0 0	0 0 0	0 0 0	0 0 0	10 5 5	0 0 0	120 360 240	3 10 7	3 7 14	1 2 5	1 1 3	4 4 12	2 4 9	1 1 2	4 20 0	6 40 20	2 2 4	2 2 2
2.8 oz)	35 20	0	0	0	0	0	0	0	40 100	2 4	280 350	8 10	8 5	3 2	2	8	5 0	1 1	270 2	10 15	2 4	0 2
ear (90 g/3.2 oz) Broccoli, 1 medium stalk (148 g/5.3 oz) Green cabbage, ½12 medium head (84	80 45	10	1 0.5	1	0	0	0	0	0 55	0 2	240 540	7 15	18 8	6	3 5	12 20	5 3	3 5	2 15	10 220	0 6	2 6
g/3.0 oz)	25 15 30	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	0 0 0	20 0 0	1 0 0	190 170 270	5 5 8	5 3 7	2 1 2	2 1 2	8 4 8	3 2 4	1 1 1	0 4 8	70 10 190	4 2 2	2 2 2
oz) Leaf lettuce, 1½ cups shredded (85 g/ 3.0 oz)	25 15	0	0	0	0	0	0	0	30	1	270 230	8 7	5 4	2 1	2	8	2	1	0 40	100 6	2 4	2

Sug-ars Pro-tein min min

min A min C cium

(%) (%)

15

Cal-

(%)

(%)

oz)

3.0 oz)

sparagus, 5 spears (93 g/3.3 oz)	25	0	0	0	0	0	0	
¹ Raw, edible weight portion. Percent (%) Dai	ly Valu	es are l	pased o	on a 2,	000 ca	orie di	et.

Total fat

(g) (%)

Cal-

fat

Calories

ories from

 Saturated

(%) (g)

Cholesterol

(mg) (%)

Sodium

(mg) (%)

Potassium

(mg) (%)

300

 9

Total Car-

bohydrate

(g)

(%)

Dietary

Fiber

(g)

(%)

(g) (g)

Nutrition facts 1 for raw fruits and vege-

tables edible portion

Sweet Potato, medium, 5" long, 2" di-

Green onion, 1/4 cup chopped (25 g/0.9

Green (snap) beans, 3/4 cup cut (83 g/

Radishes, 7 radishes (85 g/3.0 oz)

Summer squash, 1/2 medium (98 g/3.5

Asparagus, 5 spears (93 g/3.3 oz)

^{[61} FR 42761, Aug. 16, 1996]

Appendix D to Part 101—Nutrition Facts for Cooked Fish																						
Nutrition facts ¹ fish (84 g/3 oz)	Cal- ories	Cal- ories from fat	Total	fat	Saturated fat		Cholesterol		Sodium		Potassium		Total car- bohydrate		Dietary fiber		Sug- ars	Pro- tein	Vita- min	Vita- min	Cal-	Iron
			(g)	(%)	(g)	(%)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)		(g)	(g)	A (%)	(%)	(%)	(%)
Shrimp	80	10	1	2	0	0	165	55	190	8	140	4	0	0	0	0	0	18	0	0	2	15
Cod	90	0	0.5	1	0	0	45	15	60	3	450	13	0	0	0	0	0	20	0	0	2	2
Pollock	90	10	1	2	0	0	80	27	110	5	360	10	0	0	0	0	0	20	0	0	0	2
Catfish	140	80	9	14	2	10	50	17	40	2	230	7	0	0	0	0	0	17	0	0	0	0
Scallops, about 6 large or 14 small	120	10	1	2	0	0	55	18	260	11	280	8	2	1	0	0	0	22	0	0	2	2
Salmon, Atlantic/Coho	160	60	7	11	1	5	50	17	50	2	490	14	0	0	0	0	0	22	0	0	0	4
Salmon, Chum/Pink	130	35	4	6	1	5	70	23	65	3	410	12	0	0	0	0	0	22	2	0	0	2
Salmon, Sockeye	180	80	9	14	1.5	8	75	25	55	2	320	9	0	0	0	0	0	23	4	0	0	2
Flounder/sole	100	14	1.5	2	0.5	3	60	20	90	4	290	8	0	0	0	0	0	21	0	0	2	2
Oysters, about 12 medium	100	35	3.5	5	1	5	115	38	190	8	390	11	4	1	0	0	0	10	0	0	6	45
Orange roughy	80	10	1	2	0	0	20	7	70	3	330	9	0	0	0	0	0	16	0	0	0	0
Mackerel, Atlantic/Pacific	210	120	13	20	1.5	8	60	20	100	4	400	11	0	0	0	0	0	21	0	0	0	5
Ocean perch	110	20	2	3	0	0	50	17	95	4	290	8	0	0	0	0	0	21	0	0	10	6
Rockfish	100	20	2	3	0	0	40	13	70	3	430	12	0	0	0	0	0	21	4	0	0	2
Whiting	110	25	3	5	0.5	3	70	23	95	4	320	9	0	0	0	0	0	19	2	0	6	0
Clams, about 12 small	100	15	1.5	2	0	0	55	18	95	4	530	15	0	0	0	0	0	22	10	0	6	60
Haddock	100	10	1	2	0	0	80	27	85	4	340	10	0	0	0	0	0	21	0	0	2	6
Blue crab	100	10	1	2	0	0	90	30	320	13	360	10	0	0	0	0	0	20	0	0	8	4
Rainbow trout	140	50	6	9	2	10	60	20	35	1	370	11	0	0	0	0	0	21	4	4	6	2
Halibut	110	20	2	3	0	0	35	12	60	3	490	14	0	0	0	0	0	23	2	0	4	4
Lobster	80	0	0.5	1	0	0	60	20	320	13	300	9	1	0	0	0	0	17	0	0	4	2
Swordfish	130	35	4.5	7	1	5	40	13	100	4	310	9	0	0	0	0	0	22	2	2	0	4

¹ Cooked, edible weight portion. Percent (%) Daily Values are based on a 2,000 calorie diet.

^{[61} FR 42761, Aug. 16, 1996]